

Defendants Boston Scientific Corporation and Guidant Corporation hereby submit this brief in response to the United States' Statement of Interest.

Defendants appreciate the government's interest in the development of law regarding the False Claims Act and, for the most part, take no exception to any of the government's arguments regarding the applicability of the FCA generally. Indeed, it is the Defendants' strong position that the clear requirements of the FCA dictate that Relator's Amended Complaint be dismissed, and that it is Relator who has impermissibly blurred the lines of falsity and causation in trying to allege a FCA case. Defendants are compelled to respond to the United States' Statement of Interest only to the extent necessary to clarify some mistaken interpretations concerning the positions that Defendants made in their Motion to Dismiss regarding the applicability of FCA principles to this case. Defendants would also point out that the government makes arguments that might apply in the abstract or to other defendants in other cases, but which do not apply in

this specific case. Defendants urge the Court to focus on the application of the FCA requirements to the alleged facts *of this case* based on the allegations that the Relator makes (or does not make) *in this case*.

I. RELATOR IN THIS CASE HAS NOT SATISFIED RULE 9(B) PLEADING REQUIREMENTS

In its “Statement of Interest,” the United States mistakenly states that the “Defendants argue the relator’s complaint fails to allege fraud with sufficient particularity in that relator has not identified any specific false claims resulting from defendants’ alleged conduct,” and cites to page 27 of Defendants’ brief. (U.S. Statement at 2.) Defendants do not in fact take that position on page 27 or anywhere else in its brief because Relator has failed to satisfy Rule 9(b) on so many different levels that Relator’s failure to allege an actual false claim is just one of her deficiencies. Indeed, on page 27 of Defendants’ brief, Defendants quote directly from the recent Fifth Circuit case of *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, which states that the relator must allege “particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.” *Id.* at 185. As the Defendants have noted in both their Motion to Dismiss and their Reply in this case, Relator’s Amended Complaint fails to satisfy the Rule 9(b) standard enunciated in *Grubbs* and other Fifth Circuit cases because she has failed to provide any specifics regarding her allegations. It is important to recognize also that the United States explicitly states in its Statement of Interest that the government “takes no position” as to whether Relator has in fact satisfied Rule 9(b). (U.S. Statement at 2.)

II. RELATOR IN THIS CASE HAS NOT ALLEGED FALSITY

The United States also mistakenly claims that the Defendants have asserted that “any claims submitted to federal healthcare programs for such off-label uses cannot be ‘false,’” or that

Defendants argued that federal programs are “mandated” to cover services involving off-label use. (U.S. Statement at 4.) Defendants in fact assert (correctly) that the claims submitted for Defendants’ products “*under the ‘facts’ as alleged by Relator,*” are not false. (Defs.’ Mem. at 13.)¹ Defendants do not argue (as they do not need to) that off-label promotion can never give rise to a FCA case. Understandably, Defendants are applying the “facts” of this case as they are alleged against Defendants.

Defendants also do not contest the United States’ statement that “federal healthcare programs still may deny coverage for procedures involving that medical device, including denying coverage for certain off-label uses.” *Id.* Defendants’ argument, however, is that *in this case*, Medicare specifically created billing codes to allow for the submission of claims for the very procedures at issue in this case. (*See* Defs.’ Mem. at 18-19.) Defendants also never suggested that even if a code covers a particular procedure that the government must pay for it if the procedure is not medically necessary, or that an off-label use is never material to the government’s payment decision. (U.S. Statement at 5 and 9.) Defendants’ argument on this issue never went to the medical necessity of a claim but rather whether the alleged off-label use would be material to the government’s payment decision *in this particular case*.

Finally, the Defendants do not contest the United States’ general statements regarding the possible negative repercussions of bribes paid to doctors. Defendants merely argue in their Motion to Dismiss that the Relator in this case did not adequately allege the particulars of a FCA cause of action based on an Anti-Kickback violation because she failed to identify any actual false certifications and failed to comply with Rule 9(b). Defendants did not argue, as the United States seems to suggest, that kickbacks are never actionable under the False Claims Act.

¹ The United States’ description of “investigational” or “experimental” devices is irrelevant to the case at bar as the Relator makes no allegation that Defendants’ products were not FDA-approved. Defendants take no position on the United States’ treatment of these issues, which are not germane in this case.

III. RELATOR DID NOT ALLEGE THAT DEFENDANTS CAUSED SURGEONS TO SUBMIT FALSE CLAIMS ON THE BASIS OF DEFENDANTS' ALLEGED OFF-LABEL MARKETING

Again, the United States' analysis of the requisite "falsity" needed to successfully allege a FCA premised on off-label promotion may be applicable in the abstract but does not go to the allegations made in this case. Defendants did not need to address under what circumstances "material omissions" can be actionable under the FCA, because the Relator in this case never alleged that Defendants made any material omissions. Hypotheticals of what "could well amount to a half truth" or to "material omissions" are simply not applicable when applying Rule 12(b)(6) and Rule 9(b) standards to the "facts" as alleged by Relator in this case.

IV. RELATOR IN THIS CASE HAS NOT ALLEGED MATERIALITY AND CAUSATION

The United States overstates the Defendants' arguments regarding reliance and causation. Defendants point out that, under Relator's FCA theory, she is in effect alleging that all surgeons who used Defendants' products not only lied to the government when they submitted claims for medically necessary surgeries but that they also performed medically unnecessary surgeries on patients. Defendants then contend that it is insufficient for Relator to allege that "Defendants' marketing activities could have plausibly 'caused' a doctor to perform medically unnecessary surgeries" under the facts as alleged by Relator. (Defs.' Mem. at 22). The case that the United States cites, *United States ex rel. Franklin v. Parke-Davis*, 2003 WL 22048255 (D. Mass. Aug. 22, 2003), analyzes "causation" with respect to the submission of claims by doctors, not to their determinations of the medical necessity of performing surgeries on patients. The United States

cites no cases (nor does the Relator) that impose liability on a device manufacturer for “causing” a doctor to medically certify that a surgery was medically necessary when it was not.²

CONCLUSION

For all the reasons herein and the reasons in Defendants’ Motion to Dismiss and reply brief, Defendants respectfully request the all of Relator’s claims be dismissed with prejudice as to the Relator.

Respectfully submitted,

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² The arguments United States makes in footnotes 3 and 4 of its Statement of Interest have been addressed in Defendants’ Motion to Dismiss and Reply to Relator’s Opposition and will not be repeated here. The point that the United States makes in its final paragraph, namely that claims may be “false” if they are either medically unnecessary or tainted by a kickback has been addressed in Section II above.

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing document was electronically filed and service accomplished automatically through the Notice of Electronic Filing filed by the Court's Electronic Case Filing (ECF) System to all counsel of record on June 16, 2010.

/s/ Janet S. Nolan

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